



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Admistrative Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,513	03/31/2004	Ed Van Breen	5838/2002	9910
29933	7590	08/12/2008	EXAMINER	
Edwards Angell Palmer & Dodge LLP			WESTERBERG, NISSA M	
111 HUNTINGTON AVENUE			ART UNIT	PAPER NUMBER
BOSTON, MA 02199			1618	
MAIL DATE		DELIVERY MODE		
08/12/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,513	Applicant(s) BREEN, ED VAN
	Examiner Nissa M. Westerberg	Art Unit 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 May 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1, 2, 6 - 35, 39 - 44, 48 is/are pending in the application.
 - 4a) Of the above claim(s) 7, 8, 10, 11, 15, 19 - 29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 2, 6, 9, 12 - 14, 16 - 18, 30 - 35, 39 - 44, 48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 October 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review ("PTO-548") | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I, the acetate ester of HEPES, the presence of more than two surfactants, the presence of a solubilizer, the presence of a single preservative and dry eye in the reply filed on May 22, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

The fifth species election requirement for the election of the eye disorder, will be disregarded as the claims reciting specific eye disorders have been cancelled.

Information Disclosure Statement

2. The lined through documents on the IDS filed April 14, 2005 were not considered. The writing on document 3 was not legible. Additionally, 37 CFR 1.98(b)(5) requires that all documents submitted on PTO-1449 must be identified by publisher, author (if any), title, relevant pages, date and place of publication. Neither the ampoule sample nor the various product labels submitted have any of this information. Therefore, these references were not considered.

Specification

3. The specification is objected to because of the following informalities: the trade name ARLANTONE MAP in table II on p 17 could not be found. It appears this might a misspelling of the trade name ARLATONE®.

Appropriate correction is required.

Claim Objections

4. Claim 6 is objected to being of the following informalities: in line 15 of this claim, an extra period is present in phrase "about 0.1 .to 5.0%". Appropriate correction is required

Statutory Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claims 1, 6, 9, 12 – 14, 16 – 18, 30 – 35, 39 – 44 and 48 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 6, 9, 12 – 14, 16 – 18, 30 – 35, 39 – 44 and 48 of copending Application No. 11/529096. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Non-Statutory Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 6, 9, 14 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49 and 67 – 73 of copending Application No. 11/529096 in view of Murthy et al. (WO 01/07010). The recited claims of the instant application recite a controlled concentration foam cleanser composition with components (a) – (h).

The claims of '096 recite a cleanser compositions with component (a) – (i). Components (a) - (h) are the same as those recited in the instant claims. Ingredient (i) is deionized water in the range of about 50 – 99.5% by weight, a component not recited in the claims of the instant application.

Murthy et al. discloses an aqueous foam producing personal cleansing composition (abstract) with ingredients that overlap with some of the components (a) – (h), see the prepared compositions, beginning on p 11 and p 6, In 16 – p 10, In 31). Deionized water is present in the exemplary base formulations (tables I and II, p 12 and 13) as over half of the prepared composition by weight.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to add water to the composition of the instant claims, resulting in the formulation recited by claims 49 and 67 – 73 of application '096 as Murthy et al. discloses that high concentrations of water can be present in foam cleanser compositions.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112 1st Paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 6, 9, 12 – 14 and 16 – 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "zwitterionic

Art Unit: 1618

organic compound derivatives synthesized from piperazine-N' propane" and "carboxylic acid derivative of propane" do not fully meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. In claim 9, specific zwitterionic organic compounds of HEPES and in claim 18, a specific carboxylic acid derivative of propane is provided. The specification provides insufficient written description to support the genus of derivatives synthesized from piperazine-N' propane sulfonic acid or carboxylic acid derivatives of propane encompassed by the claims other than those explicitly named (e.g., acetate ester sodium salt of HEPES and citric acid), since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

11. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The presence of sodium borage-amidopropyl hydroxyphosphate, identified as a surfactant, is required in this claim. "Borage" is not a standard word used in naming chemical compounds and the compound described in this claim cannot be determined. A search of the prior art identified this compound in this and other applications with a common inventor which do not qualify as prior art.

However, because the structure of this compound could not be determined, a thorough search of the prior art for this ingredient was not possible.

Claim Rejections - 35 USC § 112 2nd Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "generated in an environment that is substantially free from a sponge" in claim 2 is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The scope of the term environment is not defined so what area is considered, and what it means to the substantially free of a sponge cannot be determined. It is not clear if the limitations of this claim would include or exclude a situation in which the foam itself was not generated using a sponge but a sponge was present by the bathroom sink where the foam was generated.

14. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 1618

regards as the invention. In the Markush group for item (d), the items "potassium lauryl phosphate polysorbate 60" and "potassium tridecyl phosphate polysorbate 60" are listed. From the structure of polysorbate 60 and either potassium lauryl phosphate or potassium tridecyl phosphate (each of which also appear in the list), the Examiner was unable to determine the structure of these names as one chemical compound and wonders if Applicant means these two compounds in combination with each other.

15. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the Markush group for item (g) is "phenoxyethanol and diazolidinyl urea propylene glycol/methyl-propyl paraben". The "and" indicates what follows is the final item in the Markush group. It could not be determined if the various compounds, as separate compounds, were all present in the composition, or if all of molecules are joined in some fashion to produce one molecule. In using the specification to try and interpret the claims, it was noted that formulation A and B contain diazolidinyl urea, methylparaben and propylparaben but no propylene glycol, which based on the format present, refers to the three separate components being present in the composition.

16. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim recites the limitation "an ester of HEPES". There is insufficient antecedent basis for the abbreviation HEPES in the claim.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1, 2, 30 – 34, 39 – 43 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Viola (US 3,962,150).

Viola describes an aqueous skin cleansing composition suitable for use as a non-pressurized, aerated, low-density foam for use in personal care products (col 1, ln 5 – 10). The composition produces a relatively stable or collapsible foam, such as those that readily break or collapse under slight pressure (col 1, n 63 – 68). The compositions are placed in a non-pressurized foam dispenser (a pre-measured amount) and foams are produced (col 7, ln 33 – 48 and the examples, such as col 8, ln 47 – 50). The compositions can be used in conjunction with an applicator such as facial or toilet tissue (col 6, ln 1 – 4). Applicant has defined sponge to include a "fiber applicator of any kind" (p 6 of the instant specification), encompassing facial and toilet tissue.

"Effective for eyelid hygiene" is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As these compositions are useful for cleaning

skin, there is no indication that these compositions are not capable of performing the function of eyelid hygiene.

The limitation is claim 2 regarding the sponge is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113.**

Many of the kit claims include a requirement for instructions. This limitation is not given patentable weight absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

19. Claims 1, 2, 30 – 32, 35, 39 – 41, 44 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Faryniarz et al. (US 5,429,815).

Faryniarz et al. discloses a sprayable cosmetic product containing dialkyl ether/hydrocarbon as the propellant that upon activation of the spray nozzle, produces a thick, creamy mousse (foam; abstract). Therefore, these foams are generated using an airless foaming device, as dialkyl ether/hydrocarbon and not air is the gas used to generate the foam material. Properly formulated cleansers remove previously applied

face powder, rouge, foundation bases, eyeshadow and lip sticks (col 1, ln 10 – 12). The compositions are contained in pressurized bottle (dispenser; col 5, ln 30 – 35).

"Effective for eyelid hygiene" or "maintaining eyelid hygiene in a subject" are recitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As these compositions are useful for cleaning skin, there is no indication that these compositions are not capable of performing the function of eyelid hygiene.

The limitation is claim 2 regarding the sponge is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

MPEP 2113.

Many of the kit claims include a requirement for instructions. This limitation is not given patentable weight absent a new and unobvious functional relationship between the printed matter and the substrate. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035; *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1618

23. Claims 1, 6, 9, 12 – 14 and 16 – 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niemiec et al. (EP 1060732) further in view of Pugliese et al. (US 6,114,337), Malik et al. (WO 01/23517) and Simion (US 5,480,633).

Niemiec et al. discloses vesicle compositions containing a benefit agent that are capable of effectively depositing the benefit agents into and onto the skin, and a novel cleansing compositions with the vesicle composition (paragraph [0001]). A variety of benefit agents can be included in the composition (paragraph [0065]), including panthenol (paragraph [0062]) and inflammation inhibitors (anti-inflammatory agent; paragraph [0056]). Mixtures of beneficial ingredients fitting in a variety of categories are contemplated (paragraph [0056]). Among the components required in the vesicle system is a single chain lipid, present in an amount of about 1% to about 50% (paragraph [0031]). Among the examples of suitable compounds for this component are polyoxyethylene derivative of a fatty acid and ester such as TWEEN® 20 (paragraph [0038]). This ingredient is identified by Applicant as a solubilizer. Preservatives can also be included in the composition (paragraph [0029]). In table 3 (p 20), a composition comprising the preservatives methylparaben, propylparaben and imidazolidinyl urea (total amount by wt 0.485%), citric acid (0.185%) and sodium lauryl sulfate (6.1%) is prepared. The pH of the mixture is adjusted to 6.5 ± 0.5 (paragraph [0128]). The composition of table 5 (p 21) comprises 0.15% citric acid and 0.15% of the surfactant linoleamidopropyl PG-diammonium chloride. The pH of this composition is lower (4.0 ± 0.4).

Niemiec et al. does not teach the inclusion of component (a), component (f) or component (h) as required by claim 6 of the instant application.

Pugliese et al. discloses compounds such the sodium salt of the acetate ester of a piperazine-N'-propane sulfonic acid (component (a); see compound VI, col 8). These compounds are adapted for use in topically applied products to reduce signs of skin inflammation with improved formulation for epidermal penetration (col 2, ln 7 – 16). The addition of selected aliphatic acids permit the HEPES moiety to penetrate the skin to better effect its anti-inflammatory nature (col 2, ln 18 – 22).

Malik et al. discloses cleansing compositions that are non-irritating to the skin (p 1, ln 6 – 9). The combination of surfactants provided is mild to the skin and uses commonly available surfactants that are stable, comprises at least 0.05% or about 0.005% to about 10% of a phospholipid (p 2, ln 28 – p 3, ln 5). Among the phospholipids disclosed is lecithin, linoleamidopropyl phosphatidyl PG-dimonium chloride and stearamidopropyl phosphatidyl PG-dimonium chloride (p 4, ln 13 – 19). Preservatives can be included, including diazolidinyl urea and parabens (methyl-, ethyl-, or propyl).

Simion et al. disclose an aqueous skin rinse formulation for soap and surfactant removal consisting of a minimal amount of a water soluble nonionic surfactant such as the polyethylene oxide-condenstates of higher fatty alcohols and a polysorbate, an organic acid have a pK_a of 4.5 to 6.5 and/or a monovalent cation salt of the acid, with the formulation having a pH within the range of about 4.5 – 6.5 (col 1, ln 11 – 22). Altering the amount of citric acid present in the composition results alters the residue removal (col 6, ln 55 – col 7, ln 13). Soap and surfactant residue on the skin can cause

skin roughness, tightness and dryness (col 1, ln 31 – 36). Optimal residue removal was achieved when the pH of the composition was 5.0 (col 8, ln 41 – 59). GERMABEN® II, a preservative product containing propylene glycol, diazolidinyl urea, methyl paraben and propylparaben is a preservative that does not reduce the viscosity as much as other possible preservatives, so less thickener is required (col 8, ln 1 – 9).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition as taught by Niemiec et al. with an active ingredient with enhanced penetration and to include an acetate ester of HEPES as an anti-inflammatory agent, a compound that itself also possess enhanced penetration abilities as taught by Pugliese et al.. Further, one of ordinary skill would add phospholipids to the composition to prepare a gentle composition as taught by Malik et al. and GERMABEN® preservative as taught by Simion et al. to prevent microbial growth without effecting the viscosity of the final composition as much as other preservatives. The various cleanser formulations can have a variety of pH's, and the values taught are within those claimed by Applicant. The required amounts of the specific ingredients in a composition are result effective parameters that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). **MPEP 2144.05.**

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW